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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,923	05/14/2007	Manpreet S. Wadhwa	PC027698A	4848
28523	7590	11/28/2011	EXAMINER	
PFIZER INC. PATENT DEPARTMENT Bld 114 M/S 9114 EASTERN POINT ROAD GROTON, CT 06340			HAMUD, FOZIA M	
			ART UNIT	PAPER NUMBER
			1647	
			NOTIFICATION DATE	DELIVERY MODE
			11/28/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No. 10/583,923	Applicant(s) WADHWA ET AL.	
	Examiner FOZIA HAMUD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-15 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 11-15 is/are allowed.
- 7) ☒ Claim(s) 1-6,9 and 10 is/are rejected.
- 8) ☒ Claim(s) 7 and 8 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 12 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/31/2011</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1a. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 August 2011 has been entered.

Status of Claims:

1b. Claims 1-15 are pending and under consideration.

1c. The rejection of claims 1-15 under 35 U.S.C. 103(a) as being unpatentable over O'Conner et al, Patel, and Cleland et al, as set forth at pages 2-9 of the previous Office Action of 01 March 2011 is withdrawn. The references do not teach stable formulations below freezing or concentrations of polyethylene glycol.

Information Disclosure Statement:

2. The information disclosure statement filed on 31 August 2011 has been received and complies with the provisions of 37 CFR §1.97 and §1.98. The references have been considered as to the merits.

Claim rejections-35 USC § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1-6 and 9-10 are rejected under 35 U.S.C § 102(b) as being anticipated by U.S. Patent 6,525,102, (Chen et al. issued on 25 February 2003).

Because of the phrase “and one or more optional excipients” in claim 1, line 4, the Examiner has interpreted that the limitations after this phrase are “optional” and therefore not necessarily required for the invention.

The instant claim 1 is drawn to a formulation comprising a growth hormone, (0.1 mg/ml up to 20 mg/ml), in an aqueous solution, a buffer that maintains the pH of about 5-7, a non-ionic polysorbate surfactant and a polymer stabilizer, wherein the polymer stabilizer is a polyethylene glycol, methionine, a tonicity agent, and a preservative, wherein the formulation remains stable at least one freezing and subsequent thawing event. Claims 2-6 and 9-10 add further limit the growth hormone, the non-ionic surfactant, polymer or buffer.

Chen et al disclose liquid aqueous formulations comprising recombinant human growth hormone (0.1 mg/ml up to 20 mg/ml), citrate buffer, and a non-ionic polysorbate surfactant, wherein the pH of the formulation is from 5 to 9, (see column 9, line 44 to column 10, line 58; column 12, line 35). The Chen et al reference also teaches that methionine may be added to the formulation to inhibit oxidation of methionine residues to methionine sulfoxide, allowing greater retention of the formulated polypeptide's proper molecular form (column 10, lines 15-58). Chen et al. disclose and the use of sugars and sugar alcohols (such as mannitol and sorbitol; well-known tonicity agents) as well as alcohol preservatives, (column 11, lines 19-65 and table 6). Chen teaches

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that addition of surfactants into the composition, such as polysorbate or PEG, prevents degradation due to freeze and thawing (see column 10, line 59 to column 11, line 8).

Chen et al. indicate that polysorbate is present in a concentration of 0.001% to about 0.2% (column 11, lines 18-25).

Therefore, Chen et al reference anticipates instant claims 1-6 and 9-10 in the absence of any evidence to the contrary.

Claim Objections:

4. Claims 7-8 are objected to as being dependent upon a rejected base claim, but would be **allowable** if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claims 11-15 are allowable.

Conclusion:

6. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FOZIA M. HAMUD whose telephone number is (571)272-0884. The examiner can normally be reached on Monday-Friday: 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
11 November 2011

/Bridget E Bunner/
Primary Examiner, Art Unit 1647